National Grain and Feed Association

August 7, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 00D-1277

To Whom It May Concern:

The National Grain and Feed Association (NGFA) respectfully submits the following comments on the Food and Drug Administration's (FDA) draft document entitled, "Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds, which was published in the June 6, 2000 Federal Register.

The NGFA consists of about 1,000 grain, feed, processing and grain-related companies that operate 5,000 facilities nationwide that store, handle, merchandise, mill, process and export more than two-thirds of all U.S. grains and oilseeds. About 70 percent of NGFA member firms are small business – country elevators and feed mills. Also affiliated with NGFA are 36 state and regional grain and feed associations.

The NGFA's Mission Statement commits our Association to foster a safe, high-quality food supply for domestic and world consumers. In that context, the NGFA believes that U.S. government guidance on recommended maximum levels of naturally occurring toxins can supplement the quality-assurance efforts already in place in the industry, provided those recommendations are based upon sound science, reliable exposure data and prudent risk analysis.

It is noteworthy that FDA's guidance document states that occurrence data show that fumonisin levels in wet and dry milled corn products, as well as meat and milk products destined for human consumption, "are normally quite low" and less than the agency's recommended limits. The NGFA concurs with FDA's view that more data are needed to gain a better understanding of the human and animal health risks associated with fumonisin. As the agency notes, there is no direct evidence that fumonisins cause adverse health effects in humans "because available studies demonstrate only inconclusive associations between fumonisins and human cancer." The NGFA supports FDA's desire to obtain a more accurate understanding of fumonisin by participating in national and international workshops before deciding whether regulatory measures, such as action limits, for fumonisin are justified. We urge the agency to continue its efforts to ensure that such workshops are organized and structured in a way that fosters the dissemination of accurate and valid scientific data that have undergone proper peer review and critical analysis, and that any extrapolations of such data from selected animal species can be justified.

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FDA should be mindful when it sets action levels or regulatory limits – or even when it issues industry guidance, as is the case with fumonisin – that the agency's pronouncements are taken very seriously by the regulated industry. These levels, even if advisory in nature, may well be incorporated into contract provisions between buyers and sellers at many levels of the food and feed system. In the commercial marketplace, the logical extension of such contractual provisions is the need to have commercially available tests that are accurate, repeatable and cost-effective, as well as practical for bulk grain handling and processing operations, to determine what levels, if any, may be present in raw or processed commodities.

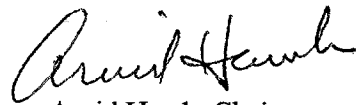
Importantly, when it comes to fumonisin, it is important that cost-effective, accurage and practical so-called "quick-test" kits (i.e., those tests based upon the ELISA technology) be available to industry. In September, the U.S. Department of Agriculture's Grain Inspection, Packers and Stockyards Administration (GIPSA) plans to begin evaluating existing commercial fumonisin "quick-test" kits to determine their accuracy and reliability which are important criteria for use in commercial transactions. However, commercial users report that these "quick-test" kits are time consuming – taking up to 30 minutes to perform a single test, twice as long as the manufacturer's claim. In addition, test kits capable of providing quantitative results can be costly, requiring an initial investment of as much as $5,000. Qualitative test kits do not require a significant initial investment but may not be suitable for some commercial transactions.

These testing hurdles could present a challenge to the industry in implementing FDA's guidance limits. Clearly, industry needs accurate and effective tools to properly analyze corn and corn products for fumonisin. We urge FDA to work closely with GIPSA, manufacturers and the industry to ensure that fumonisin "quick-test" kits are commercially practical before taking further regulatory action.

Finally, the NGFA reiterates its view that FDA should continue to rely on sound science and reliable data when issuing industry guidance, action levels or regulatory limits on toxins and naturally occurring contaminants on food and feed. When insufficient data are available to establish the health effects of a naturally occurring toxin, such as fumonisin, the NGFA believes that the prudent course of action may be for FDA to defer in issuing such recommendations. In that regard, we urge the agency to reevaluate its recommended 10 part per million guidance level for "all other species" of animals, given the paucity of data currently available.

The NGFA appreciates this opportunity to provide input on FDA's draft guidance document for fumonisin. If you have any questions on our recommendations, please feel free to contact NGFA Director of Technical Services Thomas C. O'Connor at (202) 289-0873.

Sincerely,



Arvid Hawk, Chairman
Food and Feed Safety Committee

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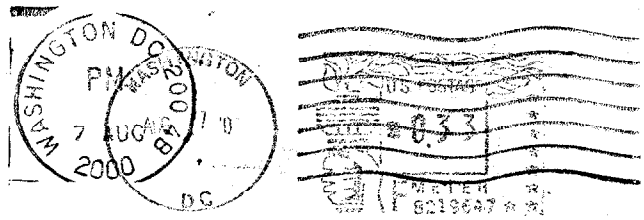

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